K080259 Page 1/4

510(k) Summary of Safety and Effectiveness for the JMEA Cannulated Bone Screw System

[This safety and effectiveness summary is provided as required per Section 513(3)(3) of the Food, Drug and Cosmetic Act]

510(k) # K080259

AUG 20 2008

1. Submitter:

Company: JMEA Corporation
Address: 1 Research Court, Suite 450
Rockville, MD 20850
Phone: 410-746-9583
Fax: 240-752-6073

2. Contact name: Sam Son, M.S.
Chief of Regulatory Compliance & Technology

3. Date of Submission: July 30, 2008

4. Name of the device: JMEA Cannulated Bone Screw System

5. Common or usual name: Interference screw

6. Classification: 21CFR§888.3040 – Smooth or Threaded Metallic Bone Fixation Fastener
21CFR§888.3030 – Single/Multiple Component Metallic Bone Fixation Appliances and Accessories

7. Predicate or legally marketed Substantially Equivalent Devices:

- Arthrex Cannulated Interference Screw (Smith & Nephew Dyonics)
- Cannulated Interference Screw System (Linvatec)
- Titanium Cannulated Interference Screw (Future Medical Systems)
- Acufex Sterile Cannulated Interference Screws (Acufex Microsurgical)

8. Material: Devices are manufactured from TI-6Al-4VELI Alloy for Surgical Implant Applications per ASTM F-136

9. Device intended use, description and substantial equivalence:

The titanium alloy screw is cylindrical with a tapered tip and has smooth single or double helix thread design.
The JMEA cannulated bone screws are used to provide interference fixation of soft tissue grafts in anterior and posterior cruciate ligament repair through arthroscopy or arthrotomy.

The screw comes in various lengths and diameters, resulting in a screw design adapted to the graft morphology and patient anatomy.

The titanium alloy cannulated interference screws and the predicate devices have the same overall design, intended use, application and material.

There are no significant differences between the JMEA Cannulated Bone Screw System and other cruciate ligament fixation systems currently being marketed, which would adversely affect the safe use of the product.

Based on the comparison of the technological characteristics of the device to the predicate and legally marketed devices, the device is substantially equivalent to other devices on the orthopedic market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 20 2008

JMEA Corporation
% Mr. Sam Son, M.S.
Chief of Regulatory Compliance and Technology
1 Research Court, Suite 450
Rockville, Maryland 20850

Re: K080259
Trade/Device Name: JMEA Cannulated Bone Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, HTN
Dated: August 20, 2008
Received: August 20, 2008

Dear Mr. Son:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K080259
Device Name: JMEA Cannulated Bone Screw System

Indications for Use:

The JMEA cannulated bone screws are used to provide interference fixation of soft tissue grafts in anterior and posterior cruciate ligament repair through arthroscopy or arthrotomy.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080259